implox Pty. Ltd.
HEALTHCARE

CUBEscan™
BioCon-700

Service Manual

Mcube
Man, Machine & Medicine
Mcube Technology Co., Ltd.

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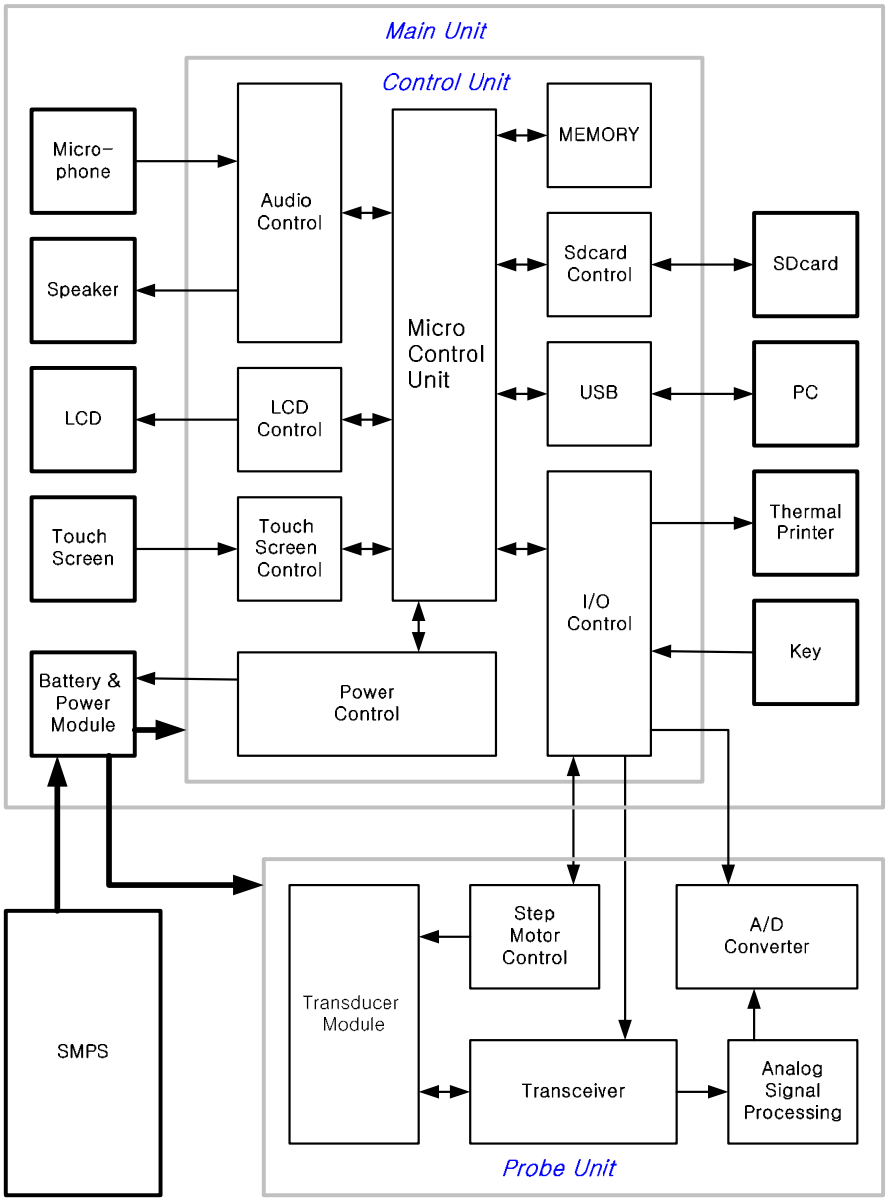
1 Product Configuration

1.1 Product configuration

BioCon-700 is a 3-dimensional ultrasonic equipment to measure the bladder volume and quantity of remaining urine safely and comfortably through non-invasive method. Its overall structure is as below.



(System Diagram of the BioCon-700)

The system, in large, consists of a console, an ultrasonic probe, and a DC adapter (power).

Component	Function
DC Adapter	Supplies a DC power required in a battery module for charging at a console.
Console	Controls system operation and various signals, and handles signal transmission and reception.
Ultrasonic Probe	Transmits and receives the ultrasonic signals, being used in close contact with the patient.

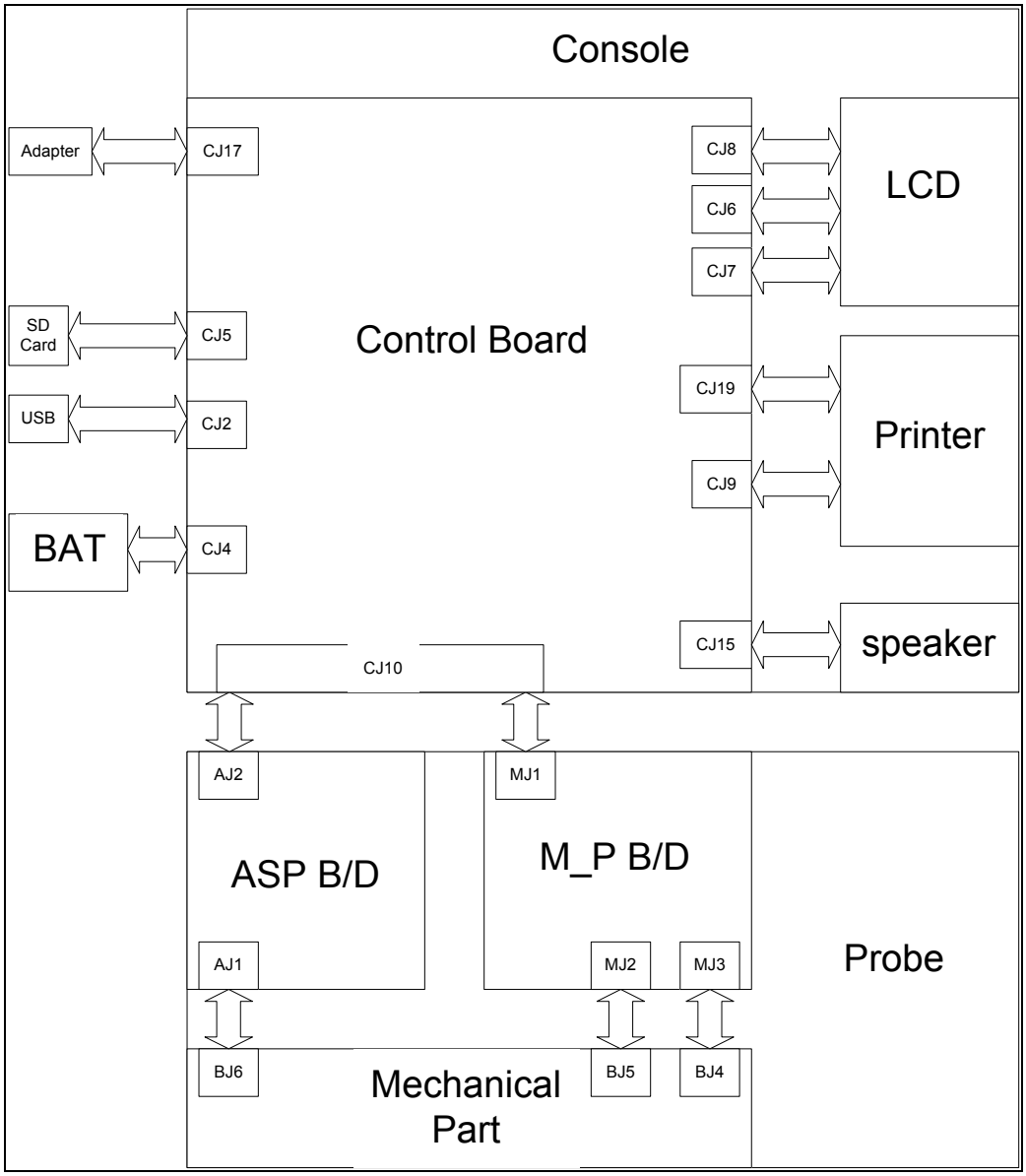
The Console consists of a printer module, an LCD module, a battery module, and a control board. Its functions are as below.

Component	Function
Control Board	Controls the overall system with following major functions. - Processes user's input. - Drives the stepping motor of the thermal printer and transmits data - Controls the charging of a battery module - Interfaces PC through USB and serial port - Displays data on LCD - Processes data received from the analog board
Battery Module	Provides the power required in the system.
LCD Module	Displays various information.
Printer Module	Prints the information about the bladder and bladder images in the thermal printer.

The ultrasonic probe consists of a cap, a connector, and an analog board. Its functions are as below.

Component	Function
Analog Board	Transmits an ultrasonic pulse to the ultrasonic probe, which processes the signal just received and transmits the data transferred through the A/D converter to the control board in the console. It also drives the stepping motor required in imaging.
Cap	Transmits ultrasonic signal
Connector	Connects the ultrasonic cable to the console

1.2 Signal Interface



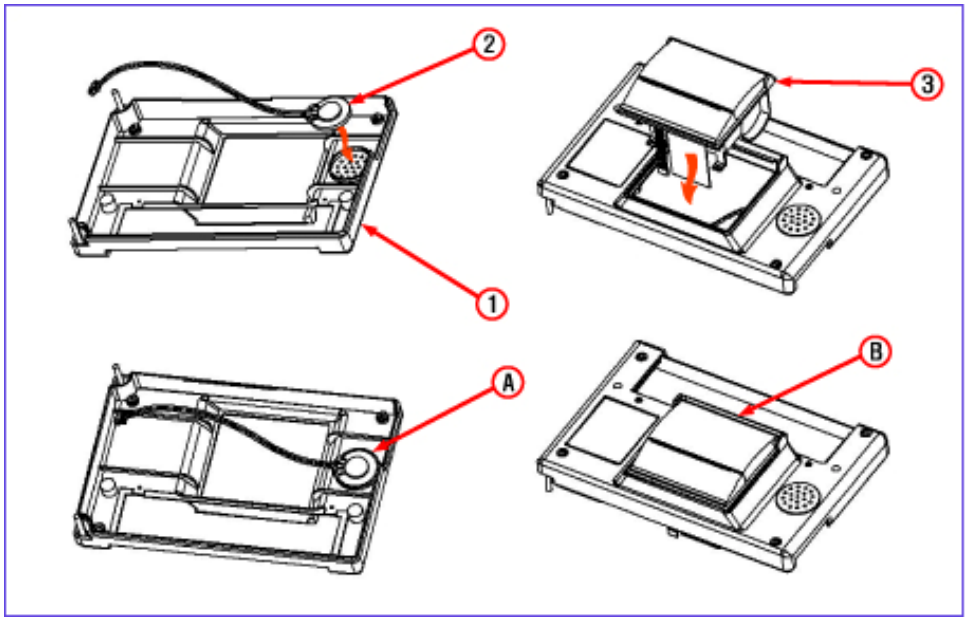
(Signal Interface of the BioCon-700)

2 Structure and Assembling of the Device

2.1 Structure and Assembling of the Bottom Case

2.1.1 Structure and Components of the Bottom Case

The basic components forming the Bottom case of the device are printer module, speaker. The basic structure is as below.



(Structure of the Bottom Case of the Device)

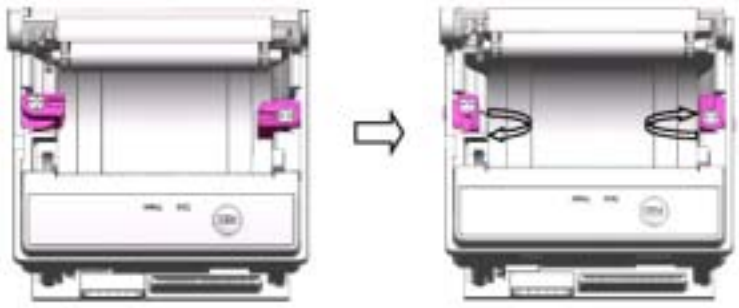
The items forming the Bottom case of the device are as below.

No.	Name	Material	Q'TY
①	Bottom case	PC-ABS	1EA
②	Speaker		1EA
③	Printer module		1EA

2.1.2 Assembling of the Bottom Case

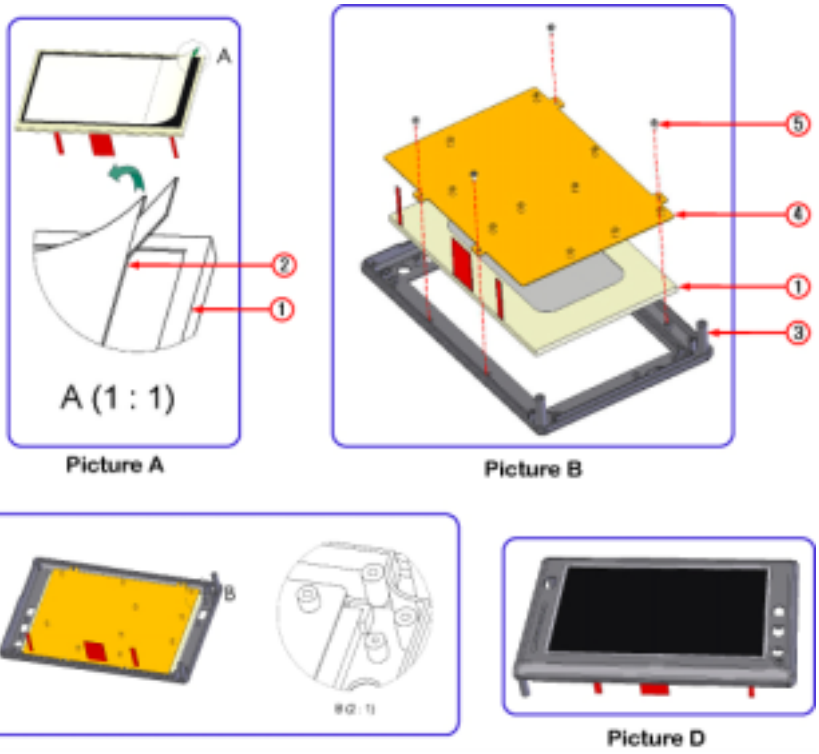
A. Interpose ② speaker into the speaker position of bottom case and fix with glue.

B. Fix ③ Printer to ① bottom case. Shown as the picture below, turn the fastener to the direction of the arrow. After it is mounted on the ① bottom case, turn and lock the fastener as it is caught to the ① bottom case.



2.2 Structure and Assembling of the Upper Case Module

The basic components forming the upper case of the device are LCD module, and switches, and LCD holder, and control B/D, and upper case. The basic structure is as below.



(Assembling of the LCD module)

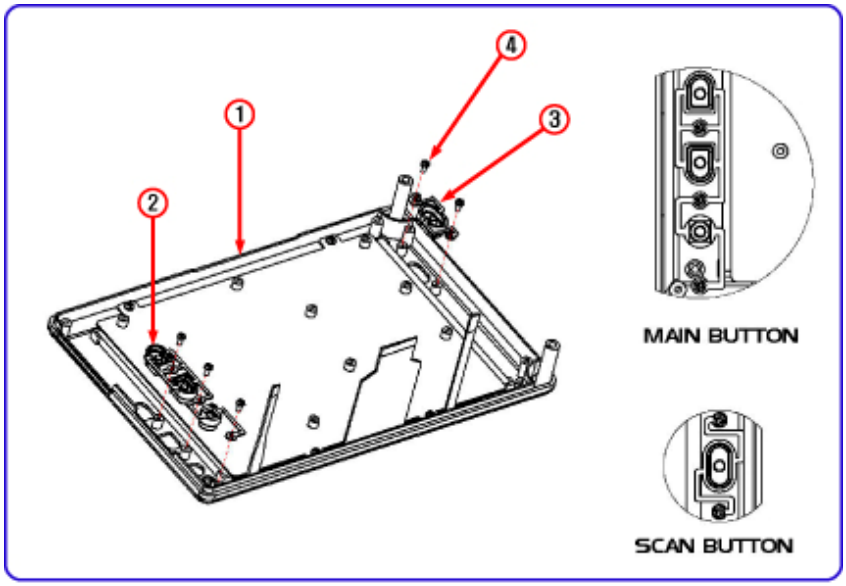
No.	Name	Material	Q'TY
①	LCD Module		1EA
②	LCD Cover		1EA
③	Upper case	PC-ABS	1EA
④	LCD Holder	Steel	1EA
⑤	M2.5X4 mm Bolt		4EA

A. Remove ② LCD Cover from ① LCD Module. (in case of new one).

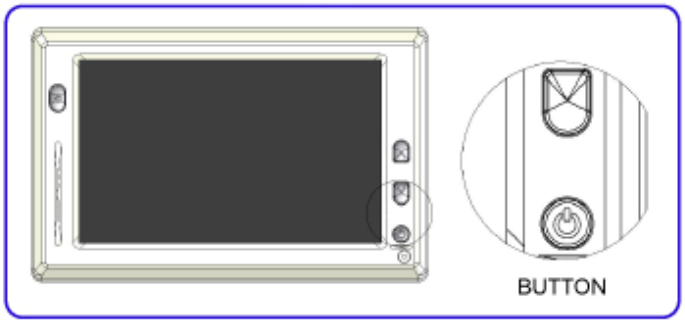
B. As shown on the Picture B, interpose ① LCD Module into the groove of ③ Upper case

C. Cover the LCD with ④ LCD Holder and fix it with ⑤ M2.5X4 mm Bolt.

2.2.1 Assembling of Buttons at the Upper Case



Picture A



Picture B

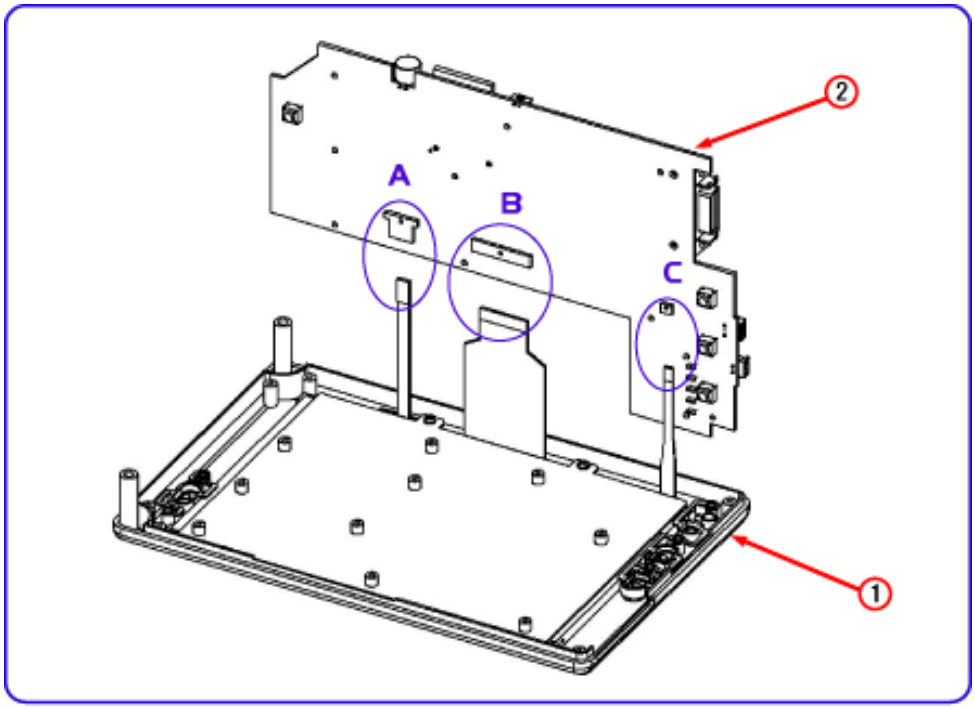
(Assembling of buttons at the upper case)

No.	Name	Material	Q'TY
①	Upper case	PC-ABS	1EA
②	Main Button	PC-ABS	1EA
③	Scan Button	PC-ABS	1EA
④	M2X4mm Bolt		4EA

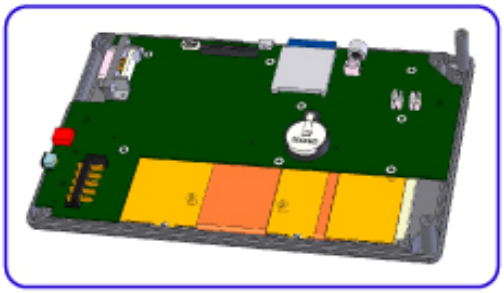
A. Put ② main button into the ① Upper case and fix it with ④ M2X4mm Bolt.

B. Put ③ Scan button into the ① Upper case and fix it with ④ M2X4mm Bolt.

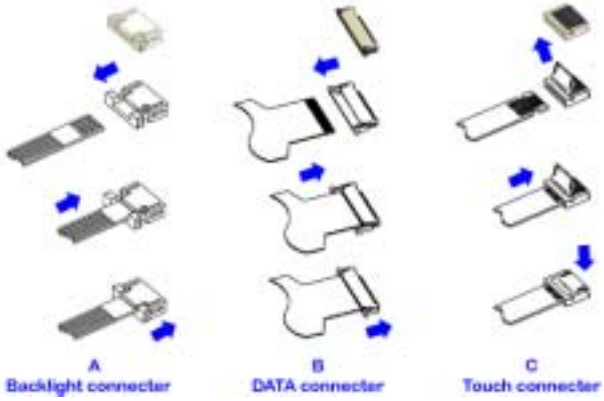
2.3 Assembling of the Control B/D



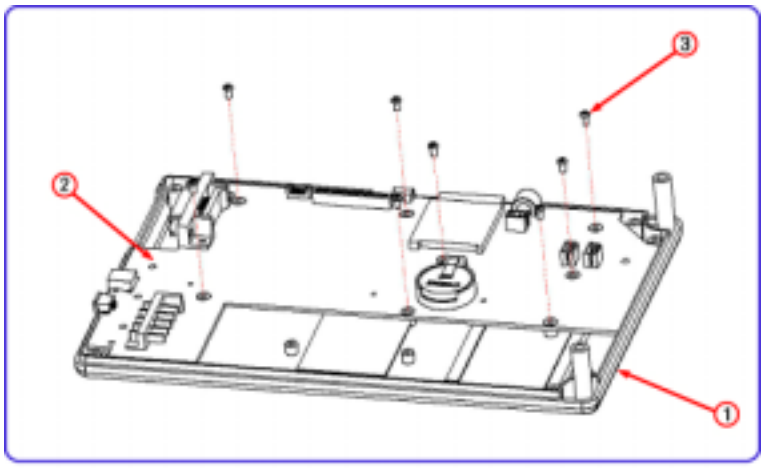
Picture A



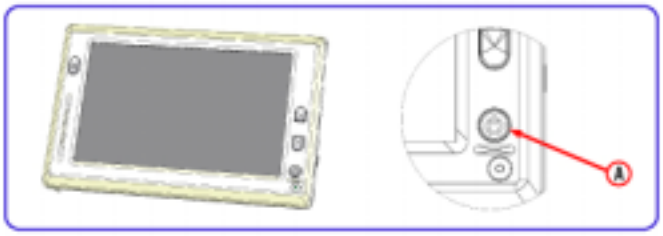
Picture B



(Connection of the connecter)



Picture A

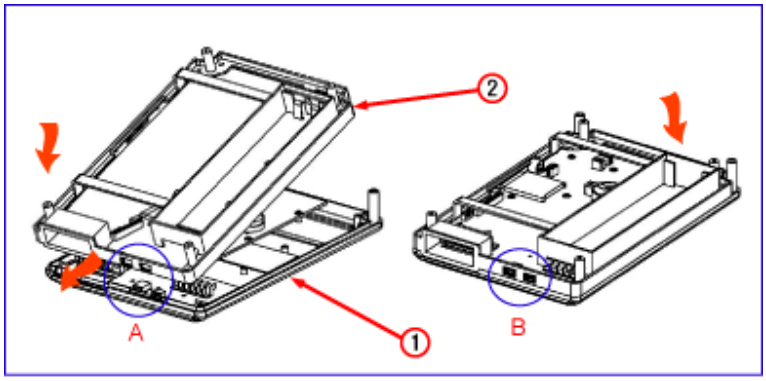


Picture B

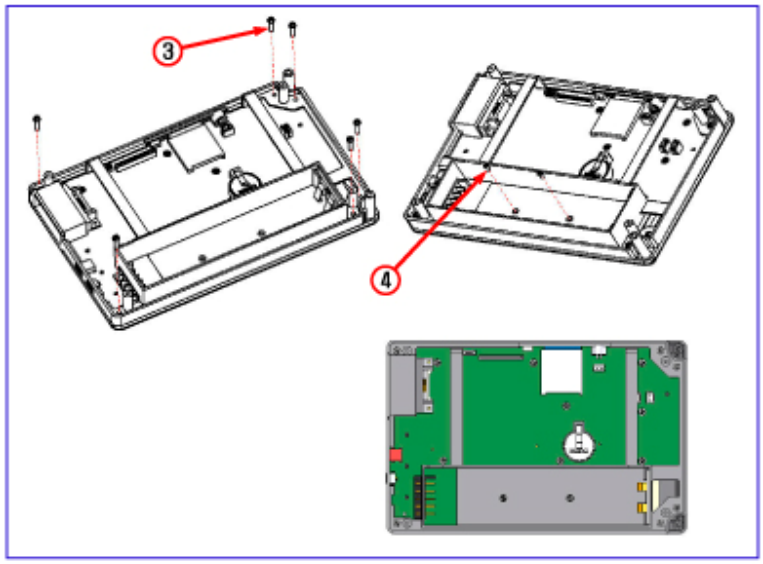
No.	Name	Material	Q'TY
①	Upper case	PC-ABS	1EA
②	Control B/D	PC-ABS	1EA
③	M2X4mm Bolt		8EA

A. Assemble the Connecters, A, B and C as shown on the picture. Mount ② Control B/D to ①Upper case and then fix it with ③M2X4mm Bolt.

2.4 Assembling of the Middle Case



Picture A



Picture B

(Assembling of the middle case)

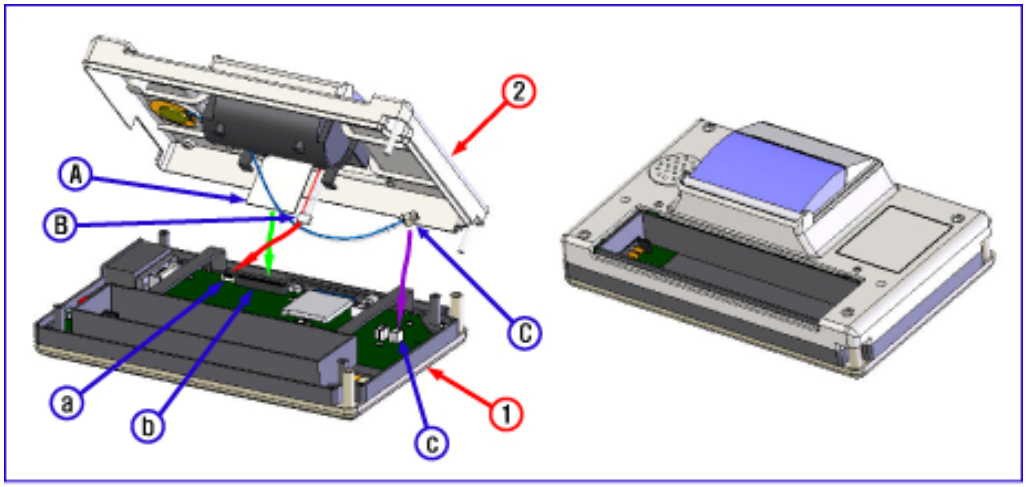
No.	Name	Material	Q'TY
①	Upper case	PC-ABS	1EA
②	Middle case	PC-ABS	1EA
③	M2.4X10mm Bolt		6EA
④	M2X4mm Flat Head Bolt		2EA

A. Put the part A first as shown on the Picture A when assemble ② Middle case to ① Upper case.

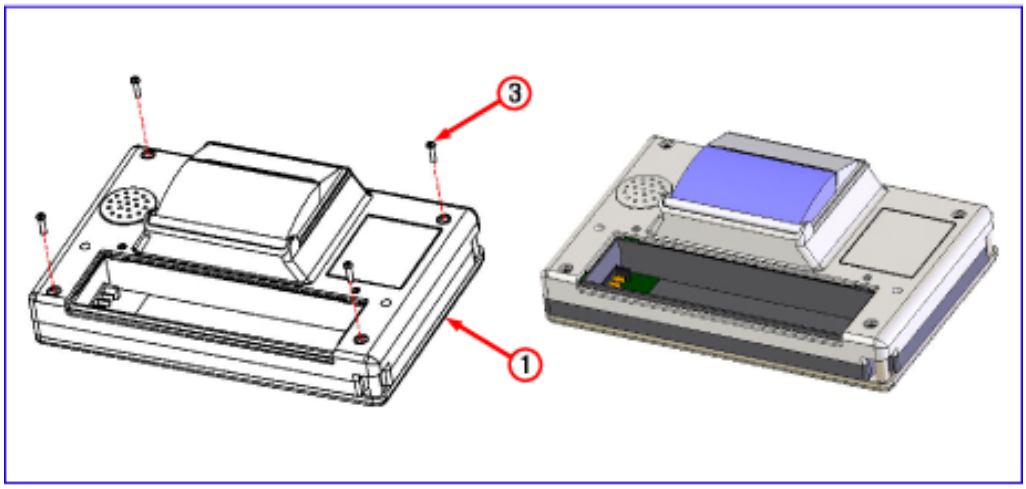
B. Fix ② Middle case with ③ M2.4X10mm Bolt.

C. Fix ② Middle case with ④ M2X10mm Flat Head Bolt.

2.5 Assembling of the Bottom Case Module



Picture A



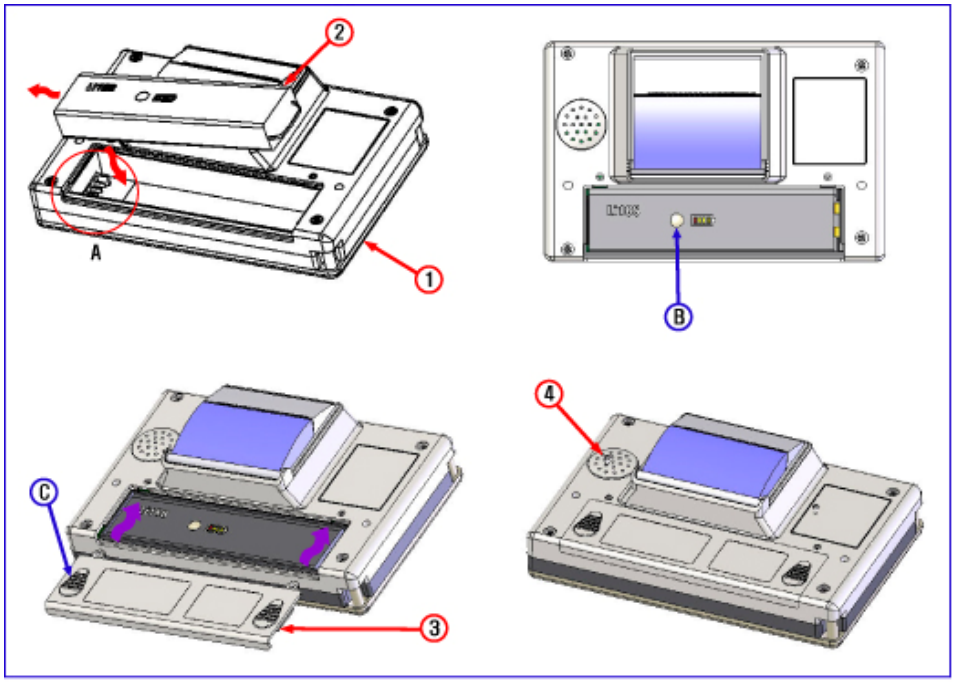
Picture B

No.	Name	Material	Q'TY
①	Upper case	PC-ABS	1EA
②	Bottom case	PC-ABS	1EA
③	M2.5X5mm Bolt		4EA

A. Link the Connection A, B and C to each corresponding socket.

B. Mount ② Bottom case first, and then fix the unit with ③ M2.5X5mm Bolt

2.6 Assembling of the Battery Cover



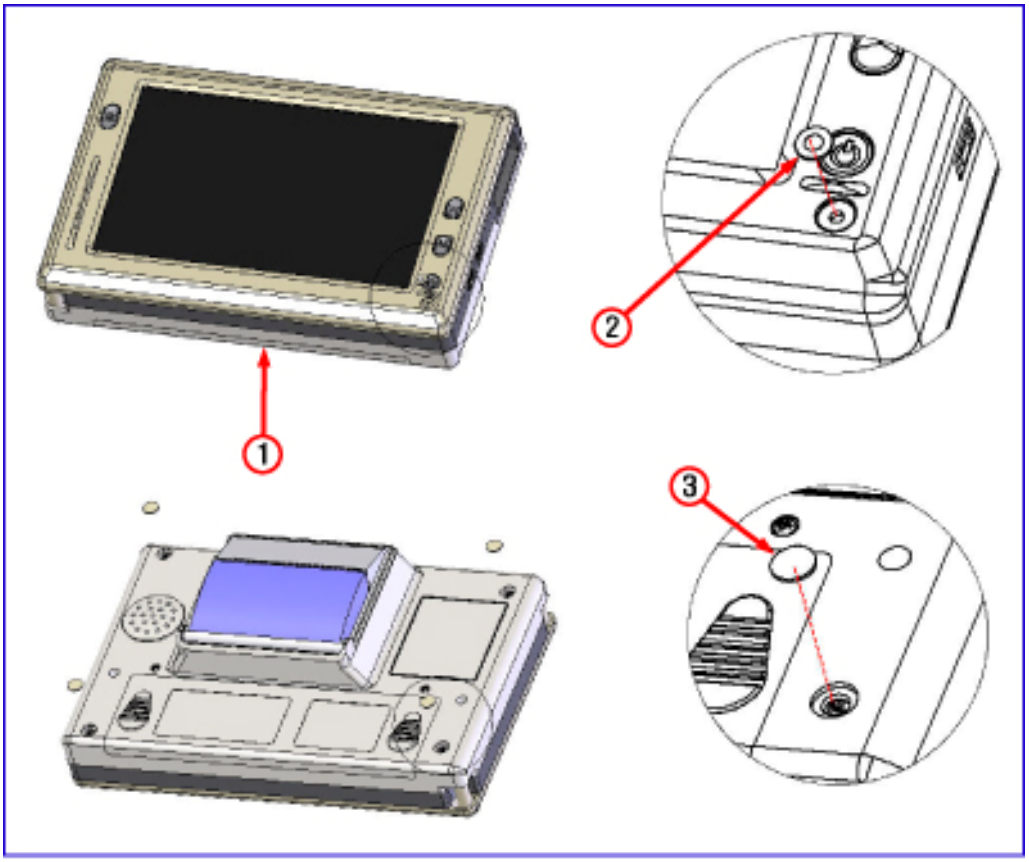
Picture A

No.	Name	Material	Q'TY
①	Console	PC-ABS	1EA
②	Battery		1EA
③	Battery Cover	PC-ABS	1EA
④	M2X 4mm Bolt		2EA

A. Put ② Battery into ① Console and then slide up ③ Battery Cover horizontally as shown on the Picture A.

B. Fix ③ Battery Cover with ④ M2X 4mm Bolt.

2.7 Cover bolt and LED hole

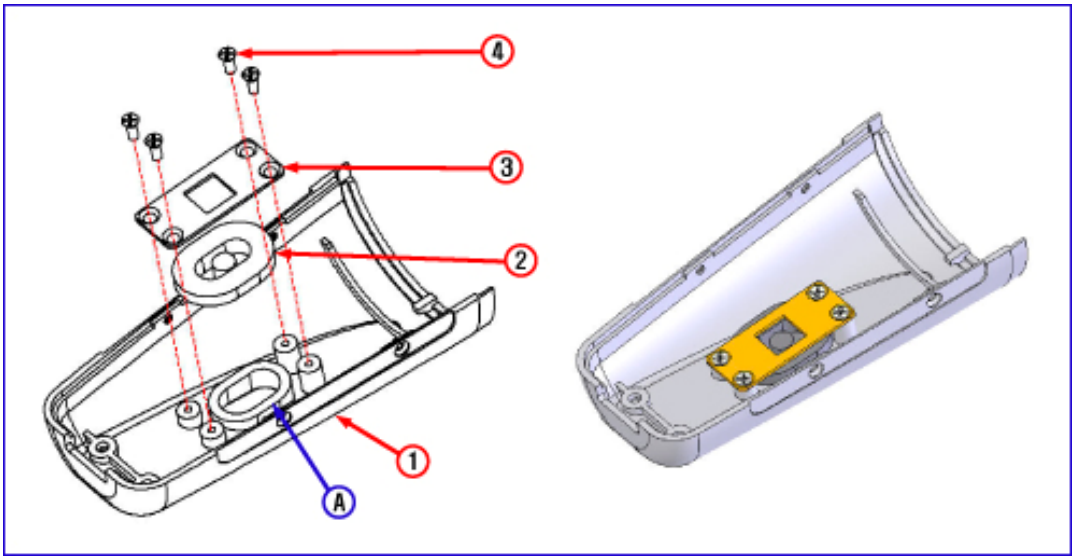


Picture A

No.	Name	Material	Q'TY
①	Console	PC-ABS	1EA
②	Urethane sheet for LED	Urethane	1EA
③	Urethane sheet for Bolt hole	Urethane	1EA

A. Cover the LED hole with ② Urethane sticker and cover Bolt holes with ③ Urethane stickers.

2.8 Assembling of the Probe Button



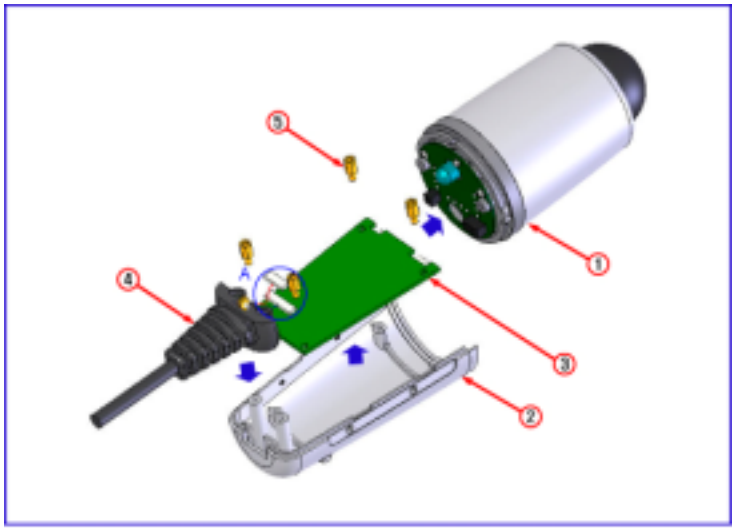
No.	Name	Material	Q'TY
①	Probe Upper Cover	PC-ABS	1EA
②	Probe Button	Silicone	1EA
③	Button Bracket	Steel	1EA
④	M2X 4mm Bolt		4EA

A. Insert ② Probe Button into the hole of ① Probe Upper Cover in right direction.

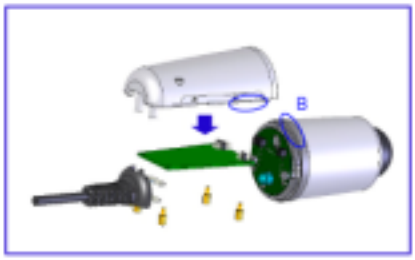
B. Fix ② Probe Button with ③ Button Bracket firmly.

C. Fix with ④ M2X 4mm Bolt.

2.9 Assembling of the Mot-Pul B/D



Picture A



Picture B

No.	Name	Material	Q'TY
①	Probe mechanical module		1EA
②	Probe Bottom Cover	PC-ABS	1EA
③	Mot-Pul B/D		1EA
④	Cable		1EA
⑤	M2.5 X 6mm Support		4EA

A. Connect 12pin connector of ④ Cable to ③ Mot-Pul B/D.

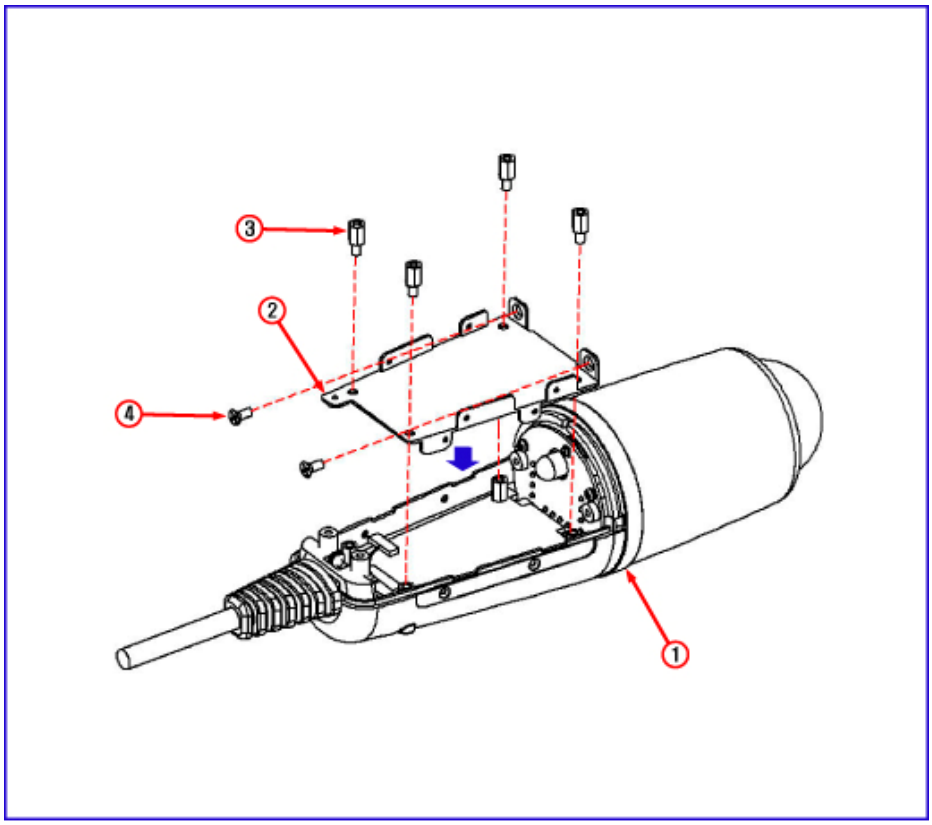
B. Assemble ④ Cable to ② Probe Bottom Cover.

C. Connect ③ Mot-Pul B/D to ① Probe mechanical module

D. As shown on the Picture B, assemble ① Probe mechanical module and ② Probe Bottom Cover.

E. Fix ③ Mot-Pul B/D to ② Probe Bottom Cover with ⑤ M2.5 X 6mm Support.

2.10 Assembling of the Metal Plate



Picture A

No.	Name	Material	Q'TY
①	Probe CKD Ⅰ		1EA
②	Probe Metal Plate	Steel	1EA
③	M2.5 X 6mm Support		4EA
④	M2.5 X 4mm Flat Head Bolt		2EA

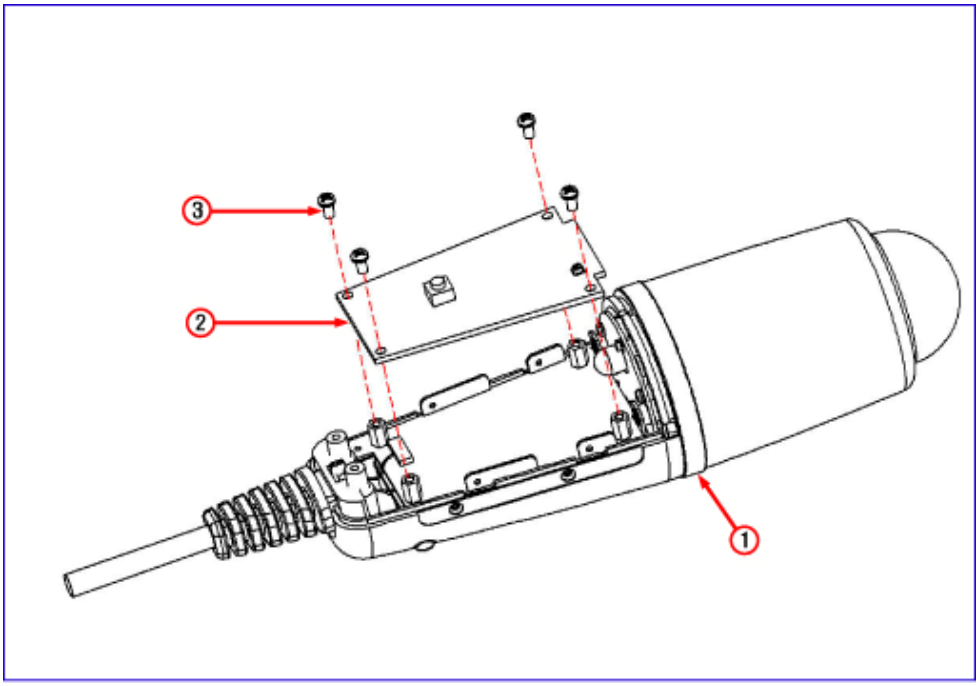
A. Place ② Probe Metal Plate onto ① Probe CKD(complete knockdown)

B. Fix ② Probe Metal Plate with ④ M2.5 X 4mm Flat Head Bolt.

C. Fix ③ M2.5 X 6mm Support as shown on the Picture A.

D. Fix the shield of Cable to ② Probe Metal Plate

2.11 Assembling of the ASP B/D



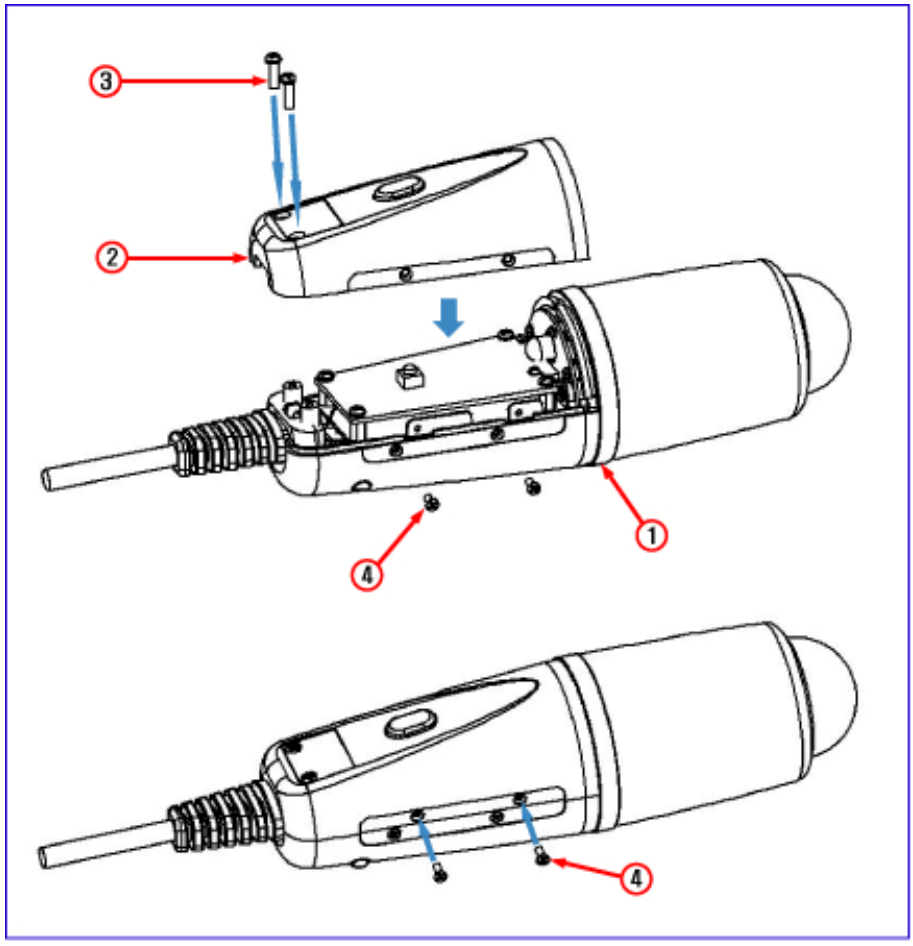
Picture A

No.	Name	Material	Q'TY
①	Probe CKD Ⅱ		1EA
②	ASP B/D		1EA
③	M2.5 X 4mm Bolt		4EA

A. Fix ② ASP B/D to ① Probe CKD II with ③ M2.5 X 4mm Bolt.

B. Connect B2B B/D and ASP B/D with Coaxial cable.

2.12 Assembling of the Upper case module



Picture A

No.	Name	Material	Q'TY
①	Probe CKD Ⅲ		1EA
②	Upper case module	Steel	1EA
③	M2 X 4mm Bolt		2EA
④	M2 X 4mm Flat Head Bolt		8EA

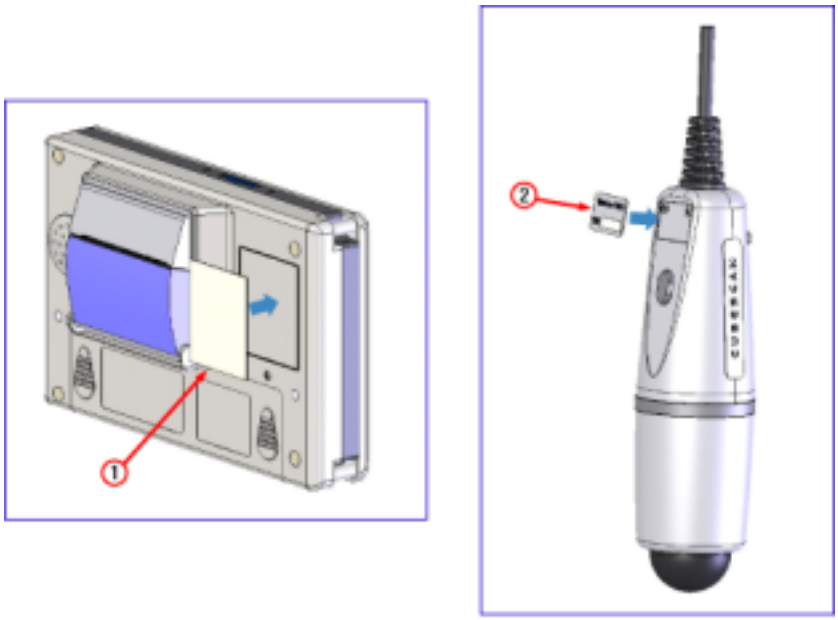
A. Assemble ① Probe CKD III and ② Upper case module.

B. Fix ① Probe CKD III and ② Upper case module with ③M2 X 4mm Bolt and ④ M2 X 4mm Flat Head Bolt.

2.13 Attaching urethane sheets and labels

Picture A

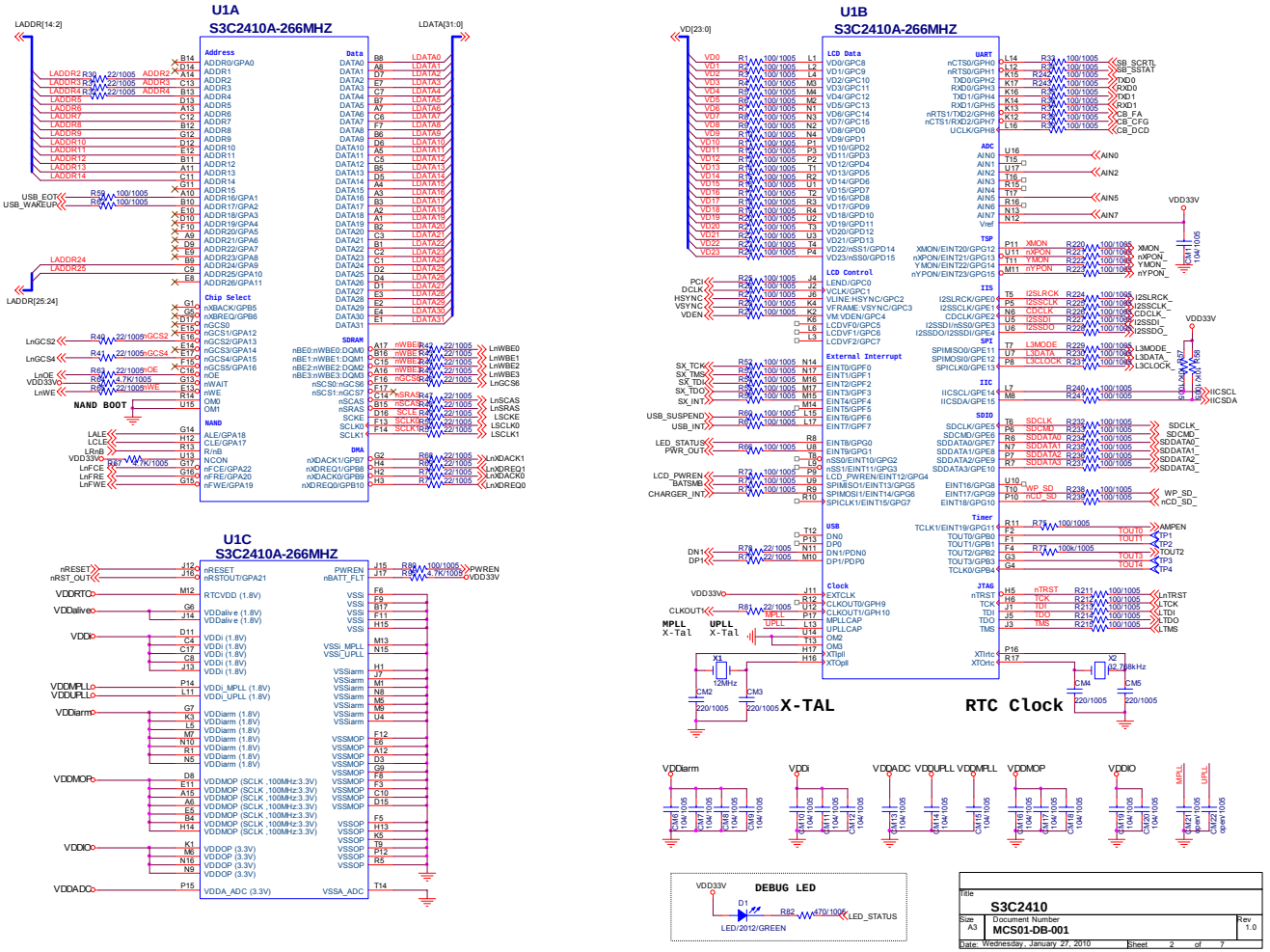
A. Attach the ② Urethane labels to ① finished Probe as shown on the Picture A.

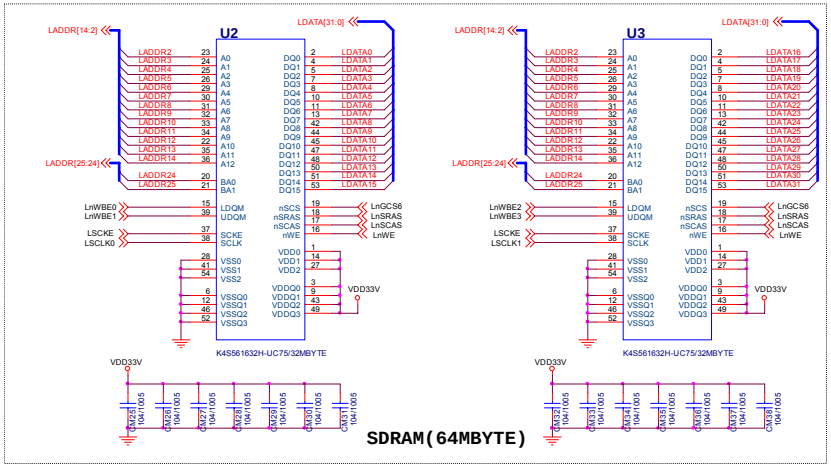


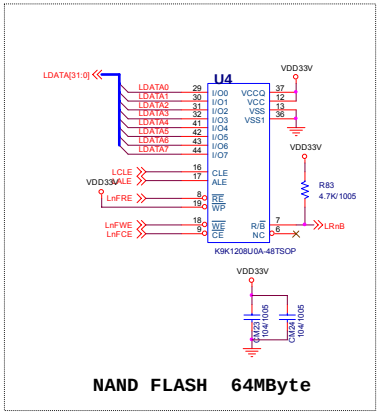
Picture A

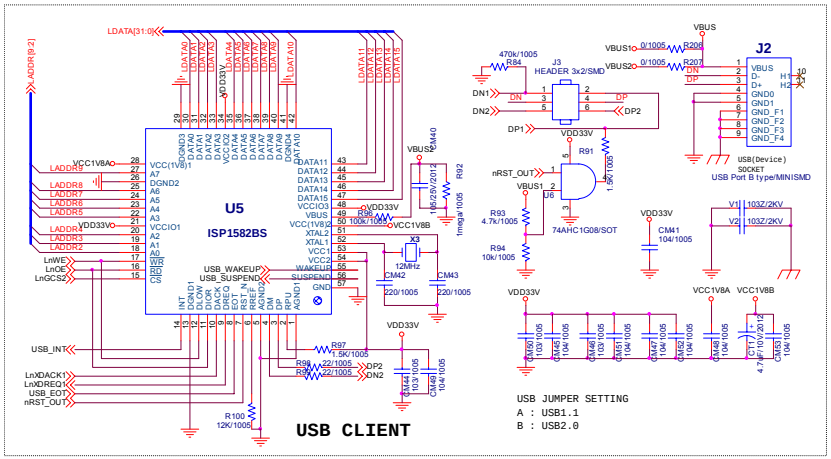
A. Shown as above Picture A, attach the label on the finished Probe and Console.

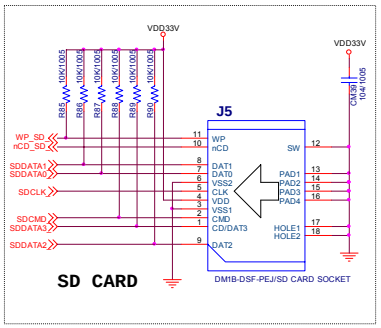
3 Circuit Diagram











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Size A3	Document Number MCS01-DB-002	Rev 1.0
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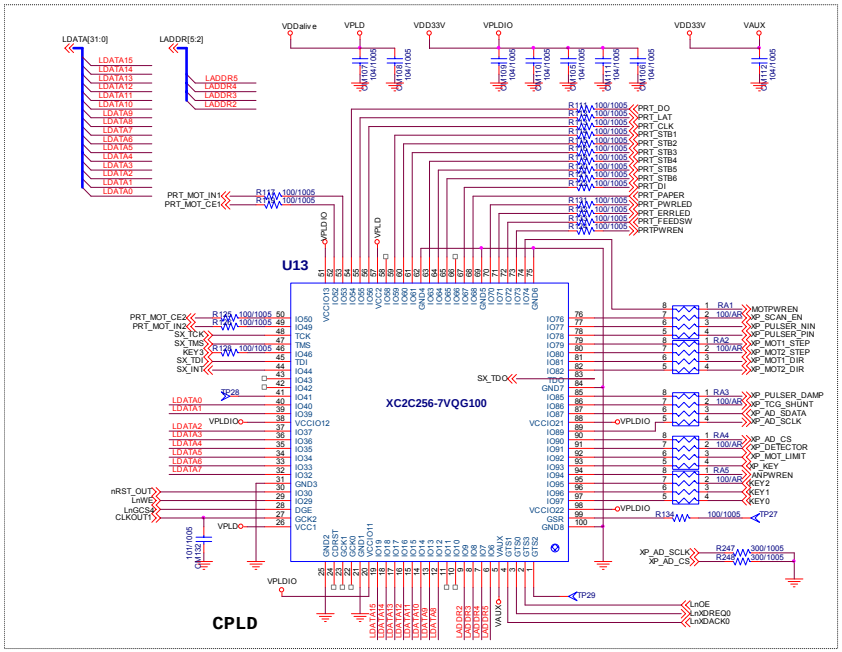

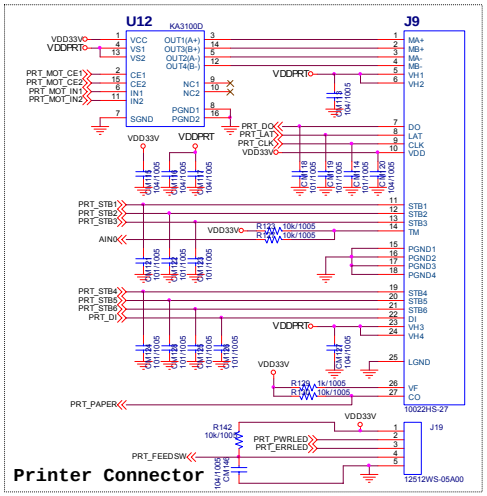

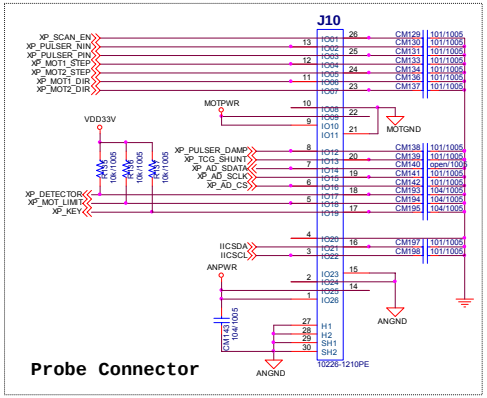

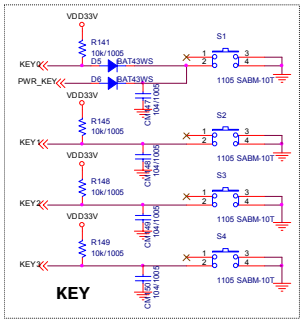

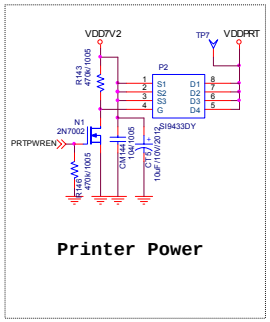

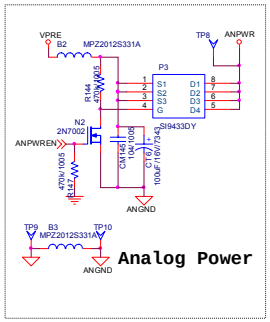

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Size A3	Document Number MCS01-DB-004	Rev 1.0
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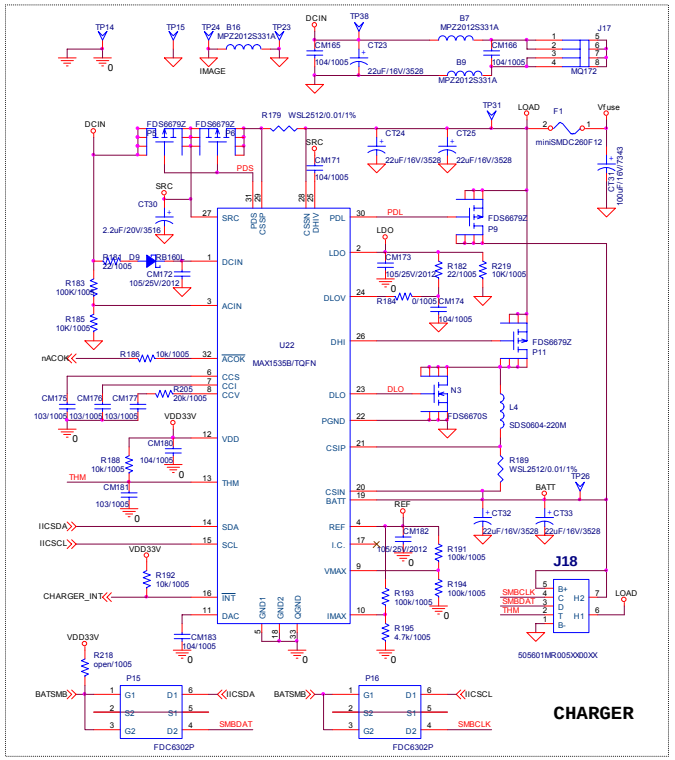

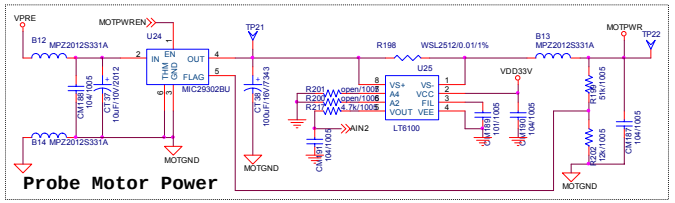

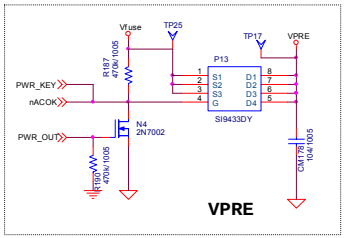

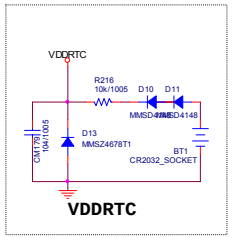

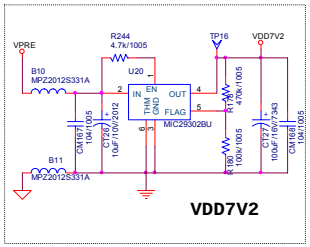

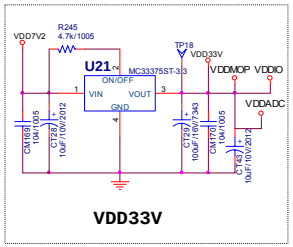

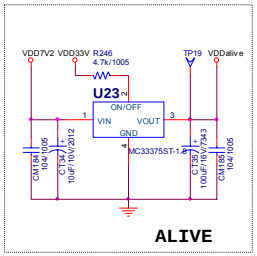

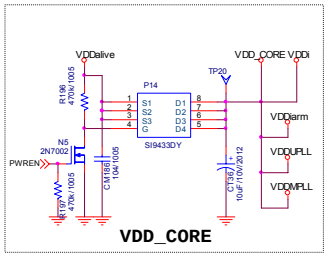

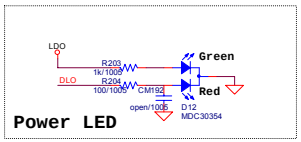

Title	POWER	
Size A3	Document Number MCS01-DB-006	Rev 1.0
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4 Device Setup

4.1 Installing or Removing the Battery

The battery is installed in a bay in the BioCon-700. When you are changing the battery or removing the battery for storage, follow these instructions.

Power off	Turn the system off.
Disconnect accessories	Disconnect all connections from the console.
	Loosen the two screws using a screwdriver.
	Remove the battery cover. IMPORTANT: When removing the battery cover, be careful to not bend the cover.
	Pull out the battery using the strap on the battery.
	Insert the new battery. When inserting, the top side of the battery (the side having LED) should be up (facing the bottom of the unit) and the strap on the battery should be in the right. The battery cannot be properly installed if the orientation is incorrect.

WARNING:	To avoid the risk of explosion, only use batteries recommended by Mcube Technology.
CAUTION:	Never use excessive force to install the battery.

4.2 Changing the Thermal Paper

	1) Open the printer cover as shown to the left.
	2) Pull out the empty bobbin.
	3) With the printer paper in one hand, unroll a small length of the paper and insert into the unit as shown.
	4) Close the printer cover after inserting the paper.

CAUTION:

- Be sure to insert the paper in the correct orientation.
- To avoid damaging the system:
  - Only use thermal paper recommended by Mcube Technology.
  - Only print when the thermal paper is correctly loaded.

4.3 Charging the Battery Module of the BioCon-700

	Connect an AC cord to a DC adapter.
	The picture shows an adapter with the AC cord properly connected.
 	Connect the DC jack to the adapter terminal of the console. *Direction of the DC jack: Check the direction of the DC jack.
	The picture shows a console with the proper connection to the DC jack.

	Connect the AC plug to a socket.
	Check the color indicator on the console. *Green in power indicator: Tells that the adapter connected and AC power is present. The system is ready to charge and be operated. *Yellow in power indicator: Denotes that the device is charging. When the battery is fully charged, the yellow indicator turns green. *Fully charging the battery may take up to approximately 6 hours..

WARNING:

- Only use AC/DC Adapters recommended by Mcube Technology.

4.4 Connecting the Probe to the System

	1. Check the direction of the probe connector as shown in the left picture.
	2. Align the probe cable to the probe terminal. After aligning, push the probe cable straight in until there is a click sound.
	* To disconnect the probe from the console, push the relief clamps marked by arrow on the probe connector and pull out.

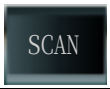
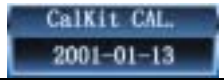
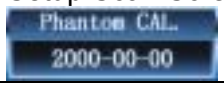
4.5 Assembling the Rolling Cart

Refer to “Rolling Cart Assemble Manual(MRC_BioCon_700)” for assembling instructions of a optional rolling cart.

4.6 Calibration

There are two methods for the calibration. Following table shows the calibration process.

Step	CalKit Calibration	Phantom Calibration
1	Open the cap of the calibration kit and pour ***saline solution*** up to the fill-mark of the calibration kit. Confirm that the air bubble is absent. You can also the pure water on behalf of the saline solution. But in this case, do calibration after confirming that all the air bubbles went away. 	Place the CubeScan phantom on a flat surface. And open the cover of the phantom.
2	Close the cap of the calibration kit. 	Drop about 5ml water to the center surface of the phantom.
3	Align the probe scan button with the arrow mark of the calibration kit, and put the probe head into the probe holder firmly.	Place the holder on the top of the Cubescan phantom. Check if the holder is in a stable and flat position. Put the probe head into the probe holder firmly.

4	Connect the probe to the device.	
5	Turn the device on.	
6	Touch the Setup icon in the Top Screen. 	
7	Touch the following icon in the Setup Screen. 	
8	Touch the following icon in the Setup Scan Screen. 	Touch the following icon in the Setup Scan Screen. 
9	Wait until the calibration is completed. If calibration is done successfully, the calibration date will be changed. If calibration error is occurred during calibration, contact a local distributor or Mcube Technology.	

5 TROUBLESHOOTING

5.1 Troubleshooting

Error message	Description	Actions
BATTERY LOW!!!	Battery low	Use again after charging the battery. IMPORTANT: To lengthen lifetime of the battery charge the battery when battery capacity is around 20%.
NO PAPER!	Printer error	1. Check if the cover of the printer is open. If the cover is open, close the cover and try printing again. 2. Check if the thermal paper is empty. If there is no paper, insert a new roll paper and try printing again. 3. After the above actions the same trouble happen, contact authorized technical center.
NO SCANHEAD!	connection error	Check if the connection between the probe-terminal in a console with the probe connector is firm. If the trouble is continued even in a proper connection, contact authorized technical center.
!ERROR! !IN CABLE CONNECTION!	Transducer circuit open	Contact a local distributor or authorized technical center.
Mismatched Ultrasonic Probe!	Wrong probe attachment	Contact a local distributor or authorized technical center.
No SD card!	No SD card installed in a SD card slot	Use after installing the SD cart to the SD card slot.
Unformatted card!	Use of unformatted card.	Use after formatting(FAT32)
Wrong file name	Invalid character as a file name	Use valid character as a file name. Do not use following characters as a file name. \ / : * ? “ < > |
Failure in reading	Read error in SD card	Try after reformatting the SD card or use another SD card.
Failure in writing!	Write error in SD card	Try after reformatting the SD card or use another SD card.
Abnormal probe motor !	Angle motor error	Contact a local distributor or authorized technical center.

5.2 Message for alert

Message	Description
Delete this file?	Check for the file deletion.
The data has been saved “Filename”	To notice that the data is saved as a “Filename”
Recorded the file exist Do you re-record voice?	When there is a annotated voice recording to the current data.
Cannot find the file!	There is no file with that name
Duplicate file name	There is a file with same name.
Not enough space in SD card!	There is not enough space in SD card.
Too long name!	Too long file name. (up to 255 characters)

6 MAINTENANCE

6.1 Battery Care

Do not overcharge the battery and avoid deep discharges. To lengthen the battery's lifetime, use the system while the battery is between 25%~75%.
The BioCon-700 does draw power from the battery even while powered off. To avoid deep discharge, disconnect the battery from the system if it will not be used for more than a week. When storing the battery, pre-charging to about 75% is recommended.

6.2 Changing the Battery Modules

See 4.1 "Installing or removing battery"

6.3 Changing the Thermal Paper

See 4.2 "Changing the thermal paper"

6.4 Cleaning & Disinfection

6.4.1 Cleaning

1) Cleaning outer case (housing) of the system

a) Wipe the main body 1~2 times using soft cloth dampened with isopropyl alcohol or any other appropriate hospital cleaning solution.. Do not allow liquids to leak into the device while cleaning..

b) Thoroughly dry the device with a clean, soft cloth before re-deployment.

2) Cleaning the probe

Since the surface of the Probe affects the result of data, users should keep as follows;

a) Before you using the device, you have to wipe out the probe cap cleanly 4~5 times by using soft cloth which was dampened with isopropyl alcohol or an appropriate hospital cleaning agent. Then you can use the device after drying with a dry, clean cloth.

b) Apply gel on the top of probe, position the probe on the abdomen of patient, and start scanning.

c) Try to scan at least 2 ~ 3 times to get more accurate results.

d) Remove and re-apply gel after scanning 4 ~ 5 times, to scan again.

e) Remove the residual gel on the probe's surface after scanning finished.

f) Move carefully not to drop the probe off.

WARNING:	● To avoid electric shock disconnect the system from the AC mains and the battery.
CAUTION:	● Do not immerse the console or the probe. ● Do not use harsh, corrosive chemicals (e.g. hydrochloric acid, bleach).

6.4.2 Disinfection

1) Disinfection of the Probe

a) Clean the Probe prior to disinfection.
b) Dampen a soft cloth with disinfected solution listed in the table below.
c) Wipe the probe with a dampened cloth.
d) Air dry or towel dry with a soft, clean cloth.
e) Inspect the Probe and the cable for any damage such as cracks.

WARNING:
- To avoid electric shock disconnect the system from the AC mains and the battery

CAUTION:
- Do not immerse the console or the probe.

Disinfectants Lists for the Probe disinfection

Use any glutaraldehyde based disinfectant to disinfect the Probe. Following table lists compatible disinfectants.

Disinfection Solutions	Type	Country of Origin	Manufacturer
Cidex	Liquid	USA	Johnson & Johnson
Cidex 7	Liquid	USA	Johnson & Johnson
Metricide 14	Liquid	USA	Metrex Research Inc.
Metricide 28	Liquid	USA	Metrex Research Inc.

CAUTION:
- Do not use Cidex Plus or Metricide Plus 30 to disinfect the device. Cidex Plus or Metricide Plus 30 will attack and damage the plastic enclosure. This will be considered as abuse and will void the warranty.

6.5 Weekly Inspection

a) Try to scan with the probe disconnected, check if the “NO SCANHEAD” message is displayed on the main display.
b) Thoroughly inspect the probe for cracks or leakage.
c) Inspect the probe cable for any damage.
d) When scanning, check for any abnormal noise emanating from the probe head.

6.6 Device Repair

Faults not described in section “6. Troubleshooting” are intended to be serviced by a certified technician. In the event a situation outside of those described in the section occurs, contact an authorized servicer or Mcube Technology for servicing.

6.7 Disposal

The device and accessories may contain environmentally hazardous materials (mineral oil, lead, battery pack, etc). When they have reached the end of its useful service life, return them to the Mcube Technology, or follow your local regulations for hazardous waste disposal.

7 SPECIFICATIONS

7.1 Symbol Directory

Symbol	Description
	Type BF patient applied part (B= body, F= floating applied part)
	Attention, see the User guide.
	Direct current(DC)
	Alternating current(AC)
IPX1	Degrees of protection against the ingress of water.
	CE marked in accordance with the Medical Device Directive
	UL classification mark for Canada and the U.S.
	Collect separately from other household waste (see European Commission Directive 93/86/EEC). Refer to local regulations for disposal.
	Date of manufacture
REF	Reference number
SN	Serial number

7.2 Specification of Components

Item	Features
Power	**AC/DC Adapter:** - Model: JMW128 KA09XXXXX Input: AC 100-240V~, 50-60Hz Output: DC 9Vdc, 3A - Comply with UL 60601-1. - Only use adapters supplied by MCube Technology.
Battery	- Battery Pack: Li18S Battery cell: Li-ion rechargeable (2P-2S) - Scan: approximately 2400 scans** - Charging time: Fully charging a completely discharged battery may take up to approximately 6 hours.
Ultrasound Probe	- sector scan - 2.6MHz ultrasound frequency - B-mode scan image - scan angle : 120° - water resistance: rated at IPX1(only probe)
Transducer	- Diameter: 10mm - Resonant frequency:2.6MHz - Bandwidth: minimum 40% at 6dB - Penetration depth(normal patient): 18cm
Thermal printer	- Built in(57mm width)
Display	- 7" TFT LCD - WVGA(800×480 pixels) - 16.7 million colors
Range	- Bladder volume range: 0 - 999ml - Accuracy*: ±15%,±15ml (0 - 999ml)
External Interface	- USB 2.0 basic
Classification of protection against electric shock	- Class Ⅱ equipment - Type BF equipment
Water resistance	- Main body(Console): Ordinary equipment - Probe: rated at IPX1
Mode of operation	- Continuous operation.
Dimension	- 66(L)×202(W)×130(H) mm
Language	- English

* Accuracy: According to the scanning instruction, and scanning on a Mcube Technology tissue-equivalent bladder phantom.

** Battery operation time: - For a new battery module fully charged
- Tested on Mcube Technology's test conditions

8 ENVIRONMENTAL CONDITIONS

8.1 BioCon-700

8.1.1 Operating conditions

Condition	Description
Ambient temperature range	+10 – +40°C (+50 - +104°F)
Relative humidity	+30% – +75% non-condensing
Atmospheric pressure range	+700hPa – +1060hPa

8.1.2 Storage and transport conditions

Condition	Description
Ambient temperature range	-10 – +60°C (+14 - +140°F)
Relative humidity	+20% – +80% non-condensing
Atmospheric pressure range	+600hPa – +1060hPa

CAUTION:

- If you are not using this device more than a week, please disconnect battery from the device. Store the battery in accordance with the recommended conditions.

8.2 Battery Module

8.2.1 Battery Storage Conditions

Condition	Description
Ambient temperature range	-10 – +30°C (+50 - +86°F) ≤ 1 Year -10 – +45°C (+50 - +113°F) ≤ 3 Month -10 – +60°C (+50 - +140°F) ≤ 1 Month
Relative humidity	+20% – +80% non-condensing
Atmospheric pressure range	+600hPa – +1060hPa

CAUTION:
- Prior to storing the battery, charge it to about 75%.

CUBEscan™

BioCon-700

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